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Call to needle times after acute myocardial infarction

Delay in calling for help for chest pain

EDITOR—We agree with the central message of Rawles et al's article, that for patients with acute myocardial infarction the first medical attendant has the ideal opportunity to provide early thrombolysis.¹ Rawles et al show the massive reduction in call to needle times achieved when thrombolysis is given by the general practitioner who first attends the patient.

We audited the provision of thrombolysis in Sheffield between 1996 and 1997, and there are striking differences between our results and those of Rawles et al. The policy of Sheffield District Health Authority is to encourage patients with chest pain to call an ambulance; general practitioners are encouraged to facilitate immediate transfer to hospital and not to delay this until after visiting the patient.

Rawles et al found that 32% of patients in urban areas with acute myocardial infarction called an ambulance rather than their general practitioner. In Sheffield, 80.3% of patients called an ambulance, with a median interval between onset of pain and ambulance call of 79.5 minutes; this increased to 156.5 minutes for patients receiving a prior visit from their general practitioner.

The shortest door to needle times occurred in patients thrombolysed within the accident and emergency department (median 41.5 minutes, 58 patients); if patients were transferred to a coronary care unit before thrombolysis, the median door to needle time increased to 70 minutes (76 patients). Patients referred by their general practitioners directly to medical wards had the longest door to needle times (median 75.5 minutes, 13 patients).

The audit standard for call to needle time was achieved in 64% of our patients who called an ambulance, were taken to the accident and emergency department and were thrombolysed in the department by their first medical attendant. When patients were taken from the department to a coronary care unit before thrombolysis, the audit standard was achieved in only 29% of cases; this decreased to 11% if their general practitioner visited before transfer to hospital. The median time between calling an ambulance and arriving at hospital was 42 minutes in all groups.

The delay between onset of ischaemic pain and calling for help continues to be substantial, and further public education is

needed. Our results suggest that in urban areas, the audit standard for call to needle time is best achieved if patients call an ambulance, are taken directly to an accident and emergency department and are thrombolysed within that department by the first doctor who attends them. Transfer to a coronary care unit increases the treatment delay and drastically reduces the proportion of patients thrombolysed within the audit standard time.

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1 Rawles J, Sinclair C, Jennings K, Ritchie L, Waugh N. Call to needle times after acute myocardial infarction in urban and rural areas in northeast Scotland: prospective observational study. *BMJ* 1998;317:576-8. (29 August.)

Acute myocardial infarction at sea can be treated promptly

EDITOR—Rawles et al highlight the difficulties experienced by many rural general practitioners who aim to provide optimal care for patients with suspected acute myocardial infarction.¹ The advantages of immediate thrombolysis must always be balanced with the risks in a location remote to resuscitation facilities. The risk to benefit ratio can only be optimised if acute myocardial ischaemia is accurately diagnosed, early treatment instituted, and the complications of such treatments minimised. While early thrombolysis is clearly important, patients remote from hospital facilities may be disadvantaged by deficiencies in any of these three criteria.

We are aware that passengers on cruise liners are frequently remote from shore based hospital facilities. As the popularity of cruising increases and the passenger population is becoming predominantly older, the incidence of acute onset chest pain at sea is increasing. The medical team on a liner with 2000 passengers may expect to see 15 patients with suspected acute myocardial infarction per year. The management of these passengers provides a further challenge to the medical team.

The proximity of onboard medical services may afford early thrombolysis (passengers with chest pain are typically seen within 10 minutes by a medical officer) yet the remoteness of the liner to full shore based hospital facilities may add to the morbidity associated with the complications of thrombolysis. Some of the large liner companies

have already addressed this problem. By developing a strategy based on rapid confirmation of diagnosis and a strict protocol recognising indications and contraindications to thrombolysis, the risk to benefit ratio of treatment in this remote location can be optimised.

Technology such as satellite fax enables electrocardiographic analysis by a consultant cardiologist within 30 minutes. Routine onboard testing for troponin-I, creatine kinase MB, and transaminases is performed on some liners, with results again available in 30 minutes. This enables prompt diagnosis and commencement of thrombolysis in less than 60 minutes.

The opportunity to thrombolysed patients in these circumstances can now occur within the guidelines recommended by the British Heart Foundation.² The advantages of a diagnosis supported by rapidly obtained investigations and good resuscitation facilities mean that thrombolysis aboard liners minimises any dangers implicit in its remote location. This management may exceed the standards of many less remote locations.

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- 1 Rawles J, Sinclair C, Jennings K, Ritchie L, Waugh N. Call to needle times after acute myocardial infarction in urban and rural areas in northeast Scotland: prospective observational study. *BMJ* 1998;317:576-8. (29 August.)
- 2 Weston CFM, Penny WJ, Julian DG on behalf of the British Heart Foundation Working Group. Guidelines for the early management of patients with myocardial infarction. *BMJ* 1994;308:767-71.

In Sandwell, patients are advised to dial 999 rather than call their GP

EDITOR—We question the general validity of the conclusions of Rawles et al.¹ Although general practitioners may be best placed to initiate prompt thrombolysis in rural or semirural areas such as Grampian, most patients living in inner city or suburban areas are still best served by direct referral to their nearest district general hospital,² particularly if thrombolysis is initiated in the accident and emergency department.

In Sandwell, a deprived inner city district with a population of 290 000 and high mortality from coronary heart disease, we agreed guidelines with local general practitioners that encourage referral of patients with suspected myocardial infarction to the nearest accident and emergency department with as little direct involvement by general practitioners as possible. On receiving a call from a patient with symptoms consistent with infarction, particularly if the doctor is unable to attend within 15-20 minutes, the doctor, receptionist, or telephonist instructs the patient or carer to summon an ambulance by dialling 999. Our ambulance service gives high priority to transfer of patients with suspected infarction (including those being attended by their general practitioner), with a median response time (call to hospital arrival) of 39 minutes. In a prospective four year audit of all admissions to our coronary care unit, the proportion of patients with confirmed infarction who had been initially seen by their general practitioner fell from 45% (189/421) in the first year to 15% (67/448) in the fourth year, while the proportion admitted directly (after a 999 call or making their own way) rose from 40% (168/421) to 80% (358/448). This was associated with a reduction in median call to needle time from 121 minutes to 68 minutes (88% (394/448) treated within the 90 minutes recommended by the British Heart Foundation). During the same period, median door to needle time fell from 40 minutes to 28 minutes and median pain to needle time fell from 280 minutes to 180 minutes. Although most of our patients were admitted to the coronary care unit by doctors in the accident and emergency department, 68% (843/1240) of those receiving thrombolysis had treatment started in the accident and emergency department.

We now counsel all patients with angina, survivors of myocardial infarction, and their families to dial 999 (rather than contact their general practitioner) if they develop prolonged cardiac pain unresponsive to rest and glyceryl trinitrate. Our hard pressed general practitioners have welcomed this trend, and the dreaded avalanche of

inappropriate accident and emergency attendances has not materialised.

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- 1 Rawles J, Sinclair C, Jennings K, Ritchie L, Waugh N. Call to needle times after acute myocardial infarction in urban and rural areas in northeast Scotland: prospective observational study. *BMJ* 1998;317:576-8. (29 August.)
- 2 Ahmad RA, Bond S, Burke J, Singh SP, Watson RD. Patients with suspected myocardial infarction: effect of mode of referral on admission time to a coronary care unit. *Br J Gen Pract* 1992;42:145-7.

Author's reply

EDITOR—The initial involvement of general practitioners in the management of patients with suspected acute myocardial infarction has important advantages: they often have personal knowledge of the patient and can exercise triage; they have the authority and experience to keep patients with chest pain at home—only a minority of chest pains are due to myocardial infarction; they can give general medical care including opiate analgesia; and they can give timely thrombolytic treatment with safety (those who give such treatment should be equipped and prepared to defibrillate). In our study,¹ we found that when general practitioners in rural areas gave thrombolytic treatment the median call to needle time was 45 minutes and more than 90% of times were within the British Heart Foundation's standard of 90 minutes.² In urban areas similar times were potentially achievable when general practitioners were in attendance.

The British Heart Foundation favours a dual response of general practitioner and ambulance service—the ambulance service supporting the general practitioner with the provision of resuscitation equipment and expertise.² Ambulance support could include recording a 12 lead electrocardiogram and carrying thrombolytic agents. However, the policy of scoop and run (80% in Sheffield), in which patients are encouraged to call for an ambulance and bypass the general practitioner, has not been fully evaluated but seems not to meet the British Heart Foundation's target in most cases. Median call to needle times in Aberdeen were similar to those from several other conurbations reported in our article and are generally about 100 minutes, with only a minority of cases being less than 90 minutes. The Sheffield experience is similar—median call to needle time for the minority of patients starting thrombolytic treatment in the accident and emergency department after a 999 call was 84 minutes, and 64% were less than 90 minutes. For other patients, call to needle times were even longer. The policy of scoop and run is inappropriate in rural areas and needs reappraisal in conurbations.³

Passengers on cruise liners who develop myocardial infarction are privileged to receive medical attention within 10 minutes,

but their interests are probably not best served by delaying thrombolysis for a cardiologist's report on the electrocardiogram. Assay of biochemical markers of cardiac infarction has too low a sensitivity to be used for confirming infarction in the first few hours after symptom onset but may be helpful in ruling out infarction at a later stage.⁴

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- 1 Rawles J, Sinclair C, Jennings K, Ritchie L, Waugh N. Call to needle times after acute myocardial infarction in urban and rural areas in northeast Scotland: prospective observational study. *BMJ* 1998;317:576-8. (29 August.)
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Advertising by pharmaceutical companies in *eBMJ*

The issue should be debated properly

EDITOR—It is regrettable that the *BMJ* has taken the decision to accept advertising from the pharmaceutical industry on its website. This will serve only to undermine the spirit and intended practice of the Medicines Act and the industry code of practice that explicitly prohibits the advertising of prescription drugs to the public.

Whereas the Medicines Control Agency might think that advertising by pharmaceutical companies on the *BMJ's* website is acceptable because the intended audience is doctors and not the public, in reality far more patients will visit the online journal than read the subscription only paper version.

In the United States the impact on health of the billion dollar business of advertising prescription drugs to consumers has raised serious concerns. The implications of advertising prescription drugs to consumers must be considered, particularly in the light of rational prescribing and clinical excellence.

I urge you to reconsider your decision and to ensure that we do not slide into a situation in which the pharmaceutical industry has direct and unmanaged links with consumers before there has been a proper debate on the issue.

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Editor's response

We have severe doubts about direct to consumer advertising of pharmaceutical products and will shortly be publishing an editorial saying so. There is, however, a world of difference between advertising designed to appeal to consumers that might appear on television and advertising designed for doctors appearing on the *BMJ's* website.

About 5% of those who visit the website each week are "members of the public," which is probably about the same as the proportion reading the paper version of the *BMJ*. My own mother reads the *BMJ* in Bath public library.

In addition, those who visit the *BMJ*'s website are not, by definition, a random sample of the population. I think it highly unlikely that rational prescribing and clinical excellence will be undermined by advertisements on the website. Indeed, if we consider the site as a whole then the opposite may be the result. Advertising may allow us to continue to keep access to our site free—to both doctors and the public worldwide. The benefits of free access to a large searchable database of high quality information on all aspects of medicine will, I think, far outweigh any hypothetical risks from exposure to the public of advertising intended for doctors.

Furthermore, if there is demand we can set up the site so that visitors can either choose to accept advertising and access the site free or have no advertising and pay. Surely the Consumers' Association would support such choice?

Richard Smith *Editor, BMJ*
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Competing interest: Obviously, the income of the *BMJ* Publishing Group is likely to be affected if there is a move towards direct advertising to consumers by pharmaceutical companies, as has happened in the United States. The group is most likely to benefit if there is no such move. I am anyway paid a fixed salary that does not vary with the profits of the group.

Sentinel node biopsy in breast cancer

Effect on patients must be considered

EDITOR—Careful consideration needs to be given to the implications for breast cancer patients from the use of the unevaluated technique of sentinel node biopsy.¹ Ideally, clinical trials to refine this technique should have been done before its introduction into routine clinical practice by enthusiastic surgeons. Training courses and conferences on this topic must be timed to avoid encouraging premature introduction and wasting resources.

The possibility that sentinel node biopsy would avoid clearance of the axilla, with its attendant problems, could be seductive to both surgeons and patients. The technique holds promise of clearer prognosis and swifter assessment with minimum invasiveness. What then might the drawbacks be for patients? Consideration of the best total outcome for the patient must always be the overriding objective.

It might be useful to draw a parallel between the introduction of mammographic screening, which resulted in closer scrutiny of breast tissue, and the use of sentinel node biopsy. Screening caused the label "breast cancer" to be applied to borderline cases so that many women with non-invasive conditions which would never cause them

problems in their lifetime carried the "cancer" label with all its drawbacks, emotional and financial. By the same token, closer scrutiny of the sentinel node will cause an upstaging of the disease. Techniques such as step sections, immunostaining, and polymerase chain reaction (which can detect 1 in 10 000 cancer cells) will inevitably mean that the label "metastatic" is applied more readily, with enormous implications for the women given that label.

Foucar commented on the surprising docility of patients about the pathologist's monopoly on diagnostic terminology that links objective histopathological observations to clinical interventions.² Classifications resulting from the use of sentinel node biopsy will not only give choice of therapy but change attitudes of mind. We will therefore need to implement Foucar's recommendation to develop a new classification so that we do not transmit "more fear than knowledge into the clinical arena."

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- 1 Dixon M. Sentinel node biopsy in breast cancer. *BMJ* 1998;317:295-6. (25 July.)
- 2 Foucar E. Carcinoma-in-situ of the breast: have pathologists run amok? *Lancet* 1996;347:707-8.

Arguments for node biopsy are weak

EDITOR—Sentinel node biopsy was developed in the treatment of malignant melanoma for two good reasons—namely, reduced morbidity and possible enhanced survival. When elective regional node dissection was common practice, the technique offered a method of selecting patients for regional node dissection. Because most melanomas occur in the leg, that meant reducing the incidence of lymphoedema, which occurs after inguinal node dissection.

Two controlled trials have shown no advantage from elective regional node dissection,¹ but many large uncontrolled series have claimed a survival advantage for patients with micrometastatic nodal disease.² The concern was that the two controlled trials had not been large enough to identify a subset of patients with tumours within a given range of Breslow thickness who might benefit from regional node dissection.

However, this argument for sentinel node biopsy does not translate comfortably to the treatment of breast cancer, where the possible benefit relates entirely to post-surgical morbidity. But what morbidity? The incidence of moderate and severe lymphoedema after regional node dissection of the axilla is minimal.³ Furthermore, an experienced surgeon can perform axillary node dissection in about the same time as it takes to perform a sentinel node biopsy. Those who justify sentinel node biopsy for non-palpable screen detected carcinoma because the incidence of axillary node metastases is so low should instead consider a selective policy for node dissection. Do patients with small grade I tumours and those with invasive duct carcinomas (say less

than 1 cm) need axillary clearance? Could observation alone be used or the axilla included in the field of irradiation?

An attractive argument for sentinel node biopsy is the concept of upstaging node negative patients as a result of immunohistochemical analysis⁴ of the sentinel node, but that technique could easily be introduced to evaluate negative nodes after axillary clearance. However, we do not know the effect of micrometastatic disease on treatment and prognosis, and we are many decades away from the results of clinical trials that will determine the effect of adjuvant therapy on patients with positive sentinel nodes.

If the argument for sentinel node biopsy in breast cancer is so weak, why is there such enthusiasm? I could be uncharitable and suggest that this research will keep some academic breast units in publications for years. More ominously, the fire is undoubtedly fuelled by the companies who produce the (very expensive) gamma probes and who will currently willingly sponsor surgical and breast meetings.

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Value is already proved

EDITOR—Dixon's editorial on sentinel node biopsy in breast cancer summarises the development and expected benefits of a powerful and relatively new technique.¹

Although some important practical aspects need to be addressed, such as the method of achieving accurate intraoperative histological evaluation, extensive evidence now exists on the principal part of the technique.²⁻³ In particular, a large number of well conducted studies have compared histology after sentinel node biopsy and axillary lymphadenectomy in the same patients. Many other studies are nearing completion. Dixon is therefore unnecessarily cautious in stating that it is not yet time for "trials comparing sentinel node biopsy with standard techniques of assessing axillary node disease." These trials have already been done, and the results show that sentinel node biopsy gives an accurate indication of axillary node status in 92.3-100% of cases.⁴

Sentinel node biopsy is a robust technique that can provide accurate results by whichever method is used. Success often depends more on the skill and experience of the surgeon than on the method used. With accuracy rates for different techniques all around 95%, clinical trials comparing the techniques are neither necessary nor

possible. What is needed is arrangements within each unit to validate the techniques in their own hands before using them as the sole means of assessing the axilla.

Further studies will be helpful in answering some of the remaining ancillary issues, but it would be a disadvantage if the momentum and clinical interest that have already developed were held up as a result of Dixon's editorial.

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- 1 Dixon M. Sentinel node biopsy in breast cancer. *BMJ* 1998;317:295-6. (25 July.)
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Author's reply

EDITOR—Thornton supports my view that sentinel node biopsy should be refined in clinical trials before it is introduced into routine clinical practice. A two phase trial has been funded in the United Kingdom by the Medical Research Council; the initial phase is to show that the centres involved in the study can consistently identify sentinel nodes, and the randomised phase will compare sentinel node biopsy with standard axillary staging techniques. Within this and other ongoing studies¹ it will be possible to assess the importance of metastatic disease in lymph nodes identified only by immunohistochemical techniques.

Her comments on screening deserve comment. The recent update of the national surgical adjuvant breast project trial of ductal carcinoma in situ reports that after apparently complete excision of ductal carcinoma in situ over one quarter of women develop recurrent ductal carcinoma in situ or invasive cancer.² This rate is similar to the recurrence rate of invasive cancer treated by wide excision and implies that pathologists are not overdiagnosing ductal carcinoma in situ. It also rebuts the view that a significant number of ductal carcinomas in situ detected by screening would never cause women problems in their lifetime.³

Thomas considers that the science behind sentinel node biopsy in breast cancer is weak, whereas Beechey-Newman and colleagues feel that the evidence for its use in clinical practice is so compelling that clinical trials are neither necessary nor useful. The latest study, which used technetium labelled sulphur colloid, identified a sentinel node in only 93% of patients, and in those in whom a sentinel node was found the sensitivity was 89%.⁴ The study's authors admit that the procedure can be technically challenging and that the results varied according to the skill and experience of the surgeon. Although encouraging, these results suggest the technique requires further refinement.

As Thomas points out, sentinel node biopsy is time consuming and expensive compared with other axillary staging procedures which have been shown to accurately stage the axilla and have little postoperative morbidity.⁵ The UK study will include an economic evaluation and a comparison of morbidity with sentinel node biopsy and other axillary surgical procedures. Only when the results of this and other studies are available will it be possible to determine whether it is appropriate to introduce sentinel node biopsy into routine practice.

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Women remain confused about breast cancer

EDITOR—Lavelle and Charlton correctly identify the need for a new baseline of women's views on breast cancer.¹ A clear understanding of the fears and myths associated with the condition is useful to doctors and forms a critical component of any health education programme. A recent opinion poll conducted on behalf of Breakthrough Breast Cancer may help to shed some additional light on women's perception of the disease. MORI interviewed a representative sample of 1045 women aged over 15 years throughout Great Britain. Interviews were conducted face to face, in the women's homes in 151 sampling points.

From a list of 11 comparable conditions breast cancer emerged as the condition that women were most concerned about having (table). Overall, 56% of women cited breast cancer as one of the conditions that they most feared; the nearest runner up was cervical cancer, cited by 38%. Interestingly, breast cancer was the leading health fear in all age ranges except women aged 15 to 24. In this age group breast cancer was second to HIV (53% and 59% respectively).

The poll also revealed that 58% of women either agreed or strongly agreed with the statement that breast cancer is more likely to be inherited than caused by a person's environment, lifestyle, or behaviour. The confusion about risk factors for breast cancer extended to specifics. Unprompted, only 15% of women mentioned a healthy diet as a means of reducing risk of breast cancer. After the women were given a list of potential means of reducing risk the figure only rose to 52%.

Responses of women (n=1045) when asked to identify the two or three diseases they feared most from a list of 11

	No of women
Breast cancer	530
Cervical cancer	359
Stroke or heart disease	350
HIV or AIDS	296
Lung cancer	260
Mental illness or depression	190
Skin cancer or melanoma	163
Multiple sclerosis	144
Meningitis	140
Respiratory disease	60
Diabetes	51
Other	6
None of these	12
Don't know	24

The poll, although limited in scope, indicates the degree of fear of the disease that exists among women. This fear may hamper screening and cause delay in seeking treatment. The results also show confusion about risk factors.

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- 1 Lavelle K, Charlton A. Women's perception of breast cancer *BMJ* 1998;317:542. (22 August.)

Multiple test procedures other than Bonferroni's deserve wider use

EDITOR—Recently, Perneger tried to establish that adjustments for multiple testing are unnecessary.¹ However, the main arguments against multiplicity adjustments are based on misunderstanding of and a lack of knowledge about simultaneous statistical inference.

Firstly, Perneger equated multiple test adjustments with Bonferroni corrections. The Bonferroni procedure ignores dependencies among the data and is therefore much too conservative if the number of tests is large.² Hence, we agree with Perneger that the Bonferroni method should not be routinely used. This is, however, no argument against the use of multiplicity adjustments in general, as there are several alternative multiple test procedures which were totally ignored by Perneger.³

Secondly, Perneger argued that multiple test adjustments are concerned only with the global null hypothesis that all individual null hypotheses are true simultaneously. This is not true. The best multiple test procedures control the multiple level (also called experimentwise error rate in the strong sense), which is the probability of rejecting falsely at least one true individual null hypothesis, irrespective of which and how many of the other individual null hypotheses are true. The control of the

multiple level is the best protection against wrong conclusions and leads to the strongest statistical inference.³

Thirdly, Perneger claimed that a multiple test procedure can only lead to the rejection of the global null hypothesis without possibility of concluding which tests are significant and which are not. In fact, the contrary is true. Multiple test procedures were developed with the aim of concluding which tests are significant and which are not, but with control of the appropriate error rate.

Fourthly, Perneger said that Bonferroni adjustments should be made in studies without prespecified hypotheses. As the number of tests in such studies is often large and the Bonferroni procedure has low power, observing this rule would imply that a large number of true effects – if not all – would be overlooked. Moreover, in exploratory studies without prespecified hypotheses there is typically no clear structure in the multiple tests, so an appropriate multiple test adjustment is difficult or even impossible. Hence, we prefer that data of exploratory studies are analysed without multiplicity adjustment. However, “significant” results based on exploratory analyses should be clearly labelled as exploratory results. To confirm these results, the corresponding hypotheses have to be tested in confirmatory studies.

In confirmatory studies with a prespecified goal represented by multiple hypotheses, in which significance tests are used as statistical evaluation tools for final decision making, the use of multiple test procedures is mandatory.⁴ For this purpose, several multiple test procedures beyond the Bonferroni method have been developed,³⁻⁵ and these deserve wider use in biomedical research.

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Inequalities in health

Independent inquiry gives detailed recommendations

EDITOR—In these days when we are overwhelmed with paper it can be tempting to skip to the summary, conclusions, or recommendations. But if this is what George Davey Smith et al have done in their editorial on the *Independent Inquiry into Inequalities in Health*¹ they risk doing Sir Donald Acheson

and his colleagues an injustice and, in doing so, understating the value and practical nature of the report.

Whereas recommendation 13 is indeed to develop “policies to reduce the fear of crime and violence and to create a safe environment for people to live in,” it is preceded on pages 54 and 55 by details of highly specific measures to achieve this. Similarly, whereas recommendation 24 is for “measures to prevent suicide among young people, especially among young men and seriously ill people,” it is preceded on page 79 by a page of detail about how this can be done.

If academics no longer have time to read documents in full perhaps there is a problem.

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- 1 Davey Smith G, Morris JN, Shaw M. The independent inquiry into inequalities in health. *BMJ* 1998;317:1465-6. (28 November.)

Authors' reply

EDITOR—We are sorry that Sir Donald Acheson, the chairman of the independent inquiry into inequalities in health, thinks that we have not done justice to the report's recommendations and that we will thus discourage *BMJ* readers from using it.¹ This was not our intention. Acheson's letter, however, illustrates what we think is the main issue. In the present and foreseeable political climate the best—and maybe the only—hope of serious governmental action to tackle the inequalities in health so fully described in the report is to produce concrete and costed proposals. These, moreover, should engage as much as possible with the government's social agenda. The proposals need to be explicit enough for it to be clear where current policies are inadequate or will work against the government's declared aim of reducing inequality.

Ashton considers the degree of specification in the recommendations of the report to be adequate; we do not. Other readers must judge this issue, but the short section on crime referred to by Ashton starts: “It is beyond the scope of this Inquiry to recommend particular approaches to prevent or reduce crime.” We agree with the implication of this statement and think that it also applies to the other areas. For example, to improve equity of access to—and quality of—public transport the privatisation policies that have led to escalating public transport charges and reduced services must be changed. We find it strange that professionals in the policy domain do not recognise the need for concrete recommendations which translate directly into action.

Current understanding of the factors underlying inequalities in health is well summed up in the report's statement that “without a shift in resources to the less well off, both in and out of work, little will be accomplished in terms of reduction of health inequalities by addressing particular ‘downstream’ influences.”²¹ The prioritisation of a

discrete collection of focused proposals would provide for the future evaluation of what has and has not been done in response to the issue identified by the report. Others—such as the Joseph Rowntree Foundation—are developing clear indicators which will allow assessment of whether the government is succeeding in meeting the challenge set by the prime minister. Similar indicators, reflected in key policy priorities, could have been established by the independent inquiry, thus taking full advantage of its automatic access to government policy makers. This task will now have to be taken on by other bodies, but with lower chances of success.

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Avoiding the consequences of deep vein thrombosis

Compartment pressures should be measured

EDITOR—In his editorial on avoiding the consequences of deep vein thrombosis¹ McCollum suggests that ischaemia in the legs as a result of elevated calf compartment pressure secondary to deep vein thrombosis should be treated by high elevation and thrombolysis. High elevation is likely to induce reflex vasospasm and reduce perfusion further. It has been shown in tibial fracture that a perfusion pressure (compartment pressure minus diastolic blood pressure) of 30 mm Hg is safe to observe without the risk of acute compartment syndrome developing.² The management of ischaemia of the leg resulting from compartment syndrome induced by deep vein thrombosis should include measurement of compartment pressures with a four compartment fasciotomy if limb perfusion pressure is inadequate.

In our experience young adults with ischaemia of the leg have amputations above the knee not for the lack of elevation but because they are managed as if they had chronic vascular insufficiency. The presence of foot and skin perfusion does not exclude ischaemia of the deep muscles and nerves, and reliance on these findings often leads to a delay in appropriate surgical management.³

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- 1 McCollum C. Avoiding the consequences of deep vein thrombosis. *BMJ* 1998;317:696.
- 2 McQueen MM, Court-Brown CM. Compartment monitoring in tibial fractures. *J Bone Joint Surg* 1996;78[B]:99-104.
- 3 Gidden DJ. Thrombolytic therapy as first line management of acute lower limb ischaemia due to trauma, a warning. *Injury* 1995;25:339-40.

Patients can participate in management

EDITOR—McCollum, in his editorial, stresses the importance of reducing the long term effects of a deep vein thrombosis.¹ He fails to mention, however, the value of low dose heparin in the prevention of the condition. Many patients leave hospital with below knee or full length plaster casts after fractures or surgery. These patients are rarely told about the risks and complications of deep vein thrombosis or how this may be prevented with low dose heparin. We also need to consider this treatment in general practice when patients are confined to bed for any long period.

It is my practice to explain the risks to such patients and offer them a regimen of low dose heparin taken twice daily. The district nurse gives the initial injections, and after suitable instruction most patients manage to give their own injections. If we are to give evidence based treatment and let patients participate in management decisions the prevention of deep vein thrombosis in those at risk provides an opportunity to practise these principles. Many general practitioners, however, are reluctant to follow this practice and believe that it is inappropriate. It is rarely suggested by hospital staff, and I would like to know what colleagues in hospital and in general practice feel about this issue. Perhaps this letter might start a debate about our reluctance to offer this option to patients at risk.

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1 McCollum C. Avoiding the consequences of deep vein thrombosis. *BMJ* 1998;317:696.

Communicating risk reductions

Data were selectively used

EDITOR—Skolbekken is guilty of the same accusation he makes against others—selective use of data.¹ After stating that his purpose is to shed some light on the presentation of facts from clinical trials such as the Scandinavian simvastatin survival study (4S) (a secondary prevention study), he then proceeds to concentrate almost exclusively on the West of Scotland coronary prevention study (a primary prevention study).^{2,3} Clearly, the absolute benefit of treatment is never going to be as large in low risk primary prevention patients as it is in high risk secondary prevention patients.

To emphasise his negative message, Skolbekken also adopts exactly the tactics of which he accuses others. For example, he concentrates exclusively on mortality as a benefit of statin treatment. Of course the 4S results do not look so good if they are presented as showing the need to treat 33 patients for 5 years to prevent one death; presenting them as 11 patients to prevent one major clinical event (death, infarction, stroke, etc) changes the picture completely.² Myocardial infarctions, strokes, bypass

Benefits of cardiovascular treatments. Adapted with permission from McMurray⁵

Treatment	Condition	Events prevented	Number needed to treat for 5 years to prevent one event
Aspirin	Transient ischaemic attack	Death, cerebrovascular accident	6
Warfarin	Atrial fibrillation (primary prevention)	Cerebrovascular accident	7
Angiotensin converting enzyme inhibitor	Left ventricular dysfunction after myocardial infarction	Death from cardiovascular disease, hospitalisation for congestive heart failure	10
Angiotensin converting enzyme inhibitor	Mild heart failure	Death from cardiovascular disease, hospitalisation for congestive heart failure	8
Statin (4S)	After myocardial infarction	Death from cardiovascular disease, myocardial infarction, cardiac arrest	10
Statin (4S)	Angina	Death from cardiovascular disease, myocardial infarction, cardiac arrest	16
Aspirin	After myocardial infarction	Death from cardiovascular disease, myocardial infarction, cardiovascular accident	12
Antihypertensive treatment in elderly patients (systolic hypertension in the elderly programme)	Hypertension	Fatal or non-fatal cardiovascular events	18
Cardiac rehabilitation	Post myocardial infarction	Death	31
Statin	Asymptomatic men with increased low density lipoprotein cholesterol concentrations	Death from cardiovascular disease, myocardial infarction	42
Antihypertensive	Hypertension (diastolic blood pressure 90-109 mm Hg)	Cardiovascular accident, myocardial infarction, death	141

operations, and hospital admissions matter greatly to patients and their families. This selective use of data applies equally to the comparison between men and women, especially in the light of the long term pravastatin in ischaemic disease study and the airforce/Texas coronary atherosclerosis prevention study.⁴

Nobody would disagree that the way we present results to patients matters, and that individual risk is an important consideration. Most practising clinicians caring for patients with ischaemic heart disease would, however, present the same data from 4S in a more patient friendly and meaningful way—for example, “this trial tells us that your best chance of being alive and well in 5 years’ time is if you take a statin.” This is simple, understandable, true, and relevant.

Lastly, as with any treatment, citing absolute risk reduction in isolation is fairly meaningless. Knowing that the number needed to treat for a statin used either for primary or secondary prevention is better than most other comparable pharmacological interventions rather changes the negative perspective Skolbekken chooses to put on the benefits of these drugs (table).⁵ Knowing that many treatments in other medical and related disciplines have no evidence base is perhaps a more important issue for discussion, including with patients.

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Competing interests: JMcM has been reimbursed by several manufacturers of cholesterol lowering drugs for attending conferences, speaking, organising education, and consulting.

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One example is not enough

EDITOR—Skolbekken has rightly pointed out some of the pitfalls of reading drug advertisements naively and not taking into account the tendency for manufacturers to present the most favourable interpretation of the effects of their product, which is the aim of advertisements.¹ As he points out, the basic facts may be correct but they can be interpreted in several different ways—for example, by substituting relative for absolute risks. Practising physicians are well aware of the “spin” that is put on such data and take it into account when assimilating their message. Physicians do also obtain information about the effects of drugs from other sources such as journals.

Skolbekken, however, falls into the same error by selecting for consideration a single example of hyperbole from the *American Journal of Cardiology*²—namely, that statins are miracle drugs—and from this he concludes that there is an “overconfidence in scientific knowledge.” Whatever advertisements may claim, the drug industry is to be congratulated for developing and bringing to fruition this new and extremely useful class of drugs to treat hypercholesterolaemia. In no way are they miracle drugs: their mechanism of action is clearly understood.

Their effects result mainly from a powerful inhibition of the enzyme 3-hydroxy-3-methylglutaryl coenzyme A reductase, which is central to cholesterol synthesis. Skolbekken does not seem to appreciate that they will cause an almost invariable decrease in plasma cholesterol concentrations in hypercholesterolaemic patients but, because coronary heart disease is multifactorial, will not have a similar impact on reducing the incidence of arterial disease. This is equivalent to demanding that hypoglycaemic drugs used in diabetic patients to lower blood glucose concentrations will have a similar impact on reducing coronary artery disease.

Skolbekken is right to be concerned about the hazards of miscommunication in any field, but should not fall into the same errors that he is attacking by only presenting half the picture.

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Researchers should present results with both relative and absolute risks

EDITOR—Skolbekken has highlighted several important and general issues regarding the communication of risk, which require further elaboration.¹ One concern is drawing a distinction between communication of risk to professionals who deliver health care and communication of risk to patients. Another concern is whether it is best to present data as relative or absolute risks.

The responses of professionals and patients to information about risk are likely to differ. In both groups most people do not have specific training and have difficulty with statistical information, but it is more likely that professionals have a grounding from which their understanding of probabilistic information can be developed. This is, however, likely to be more challenging to patients. Different strategies to improve the communication of risk will be necessary for both professionals and patients. Standardising the "language of risk" may be helpful to professionals but not to patients, for whom the contextual variations are great and flexibility is required to tailor information to specific needs.^{2,3}

Concerning the presentation of risk information, Skolbekken cites many studies showing the persuasive effects of relative risk information. Incidentally most of these concern presentation of information to professionals rather than to patients, although the effects seem similar. It is worth noting that currently preferred formats for presentation of trial data in journals are as odds ratios, which are also relative comparators of outcomes. The absolute risk or probability of

key outcomes are often not given the same headline prominence (as, for example, in the studies of a potential association between neonatal vitamin K and childhood leukaemia).^{4,5} The real impact in terms of health gain is derived from absolute risk reductions (or expressed as numbers needed to treat), but it would be redressing the balance too far to say that this should now be the only way of presenting results.

Information on risks may be useful in clinical practice, but a further decision making step then follows. This may be doctor led, patient led, or shared between them, but in all situations individual preferences and values contribute. In making decisions both professionals and patients often find relative risk information and comparison with everyday familiar risks helpful.³ We suggest therefore that researchers should present results with both relative and absolute risk estimates and not present either in isolation, which may be misleading or insufficiently helpful for arriving at a decision. Such methods are nearer to the "whole truth."

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Modifying risk is different to treating illness

EDITOR—Skolbekken reviews the important issue of how the perceptions of risk reduction from cholesterol lowering drugs are strongly influenced by the way data are presented.¹ His comparison of the effectiveness of statins with that of penicillin deserves further attention. It is hard to think of a situation where an antibiotic would be of much use if its effectiveness was based on treating hundreds of patients daily for half a decade to cure the infection in one of them. Why then are statins considered to be a major therapeutic advance?

The answer perhaps lies in the difference between an illness, such as an infection, and an asymptomatic risk factor, such as moderately increased cholesterol concentrations. Managing a risk factor is about dealing with probabilities applied to populations rather than treating an illness. This seems to make a much lower likelihood of individual benefit acceptable. Because increased cholesterol concentrations are common, widespread treatment is likely to bring large benefits to the community despite offering little benefit to individuals. Rose called this

the prevention paradox, before statins were available.²

The distinction between treating an illness and modifying a risk factor has implications for both doctor and patient. For the doctor, there is a danger that modifying the risk factor can become an end in itself, obscuring the real goal of preventing future morbidity and mortality. Galton and Seed on the website (bmj.com/cgi/eletters/316/7149/1956) may have succumbed to this when they seem to suggest that a decrease in plasma cholesterol concentration is important even if it does not have a similar impact on arterial disease. For patients, their individual perspectives on the risk factor become more important. Risk is relative and can mean different things to different people, so the patient needs to be involved in putting a value on potential future benefits.³ Skolbekken, however, points out that a patient's choice may not always be what a doctor would like it to be. Presenting patients with information about the risks and benefits of cholesterol treatment may mean they do not accept treatment.⁴ This difference of opinion is about an individual's attitude to risk rather than a medical matter.

I suggest that patients should be told clearly that the aim of cholesterol reduction is to modify risk rather than to treat an illness. Only then, with knowledge about the individual patient's attitude to risk, can doctor and patient assess information about relative or absolute risk reduction.

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Author's reply

EDITOR—Critics have correctly observed that the article is based on a selection of facts, those facts selected by various proponents of statin treatment. The purpose was to illustrate how different ways of stating these facts may lead to totally different impressions from those advocated by these proponents. Disliking this, and unable to put their finger on any errors in the article, McMurray, and Galton and Seed grasp for rhetorical straws, projecting on to me a selectivity they have hitherto failed to address in the proponents' work. Furthermore, examples from both studies were used throughout my article, which makes the claim that it concentrated almost exclusively on one of them look like another case of selective reading.

Galton and Seed have faith in the abilities of practising physicians to see through advertisement "spin." Repeated evidence referred to in the article indicates that this is little more than wishful thinking.

Edwards, Elwyn, and Stott note that risk communication requires further elaboration. A major issue in this elaboration concerns the discourse on expert versus lay perceptions of risk. The existence of a "lay epidemiology"^{1,2} shows that we should not underestimate the general population's ability to handle risk information. Nor should we overestimate physicians' ability to do so. Aiming for the "whole truth" in these matters, we may also note that to focus on patients' health resources may prove as fruitful as the present discourse on risk.³

Steel draws a line between treatment of diseases and treatment of asymptomatic risk factors. He thereby faces the task of explaining how risk factors figure as diseases in the international classification of diseases and numerous other medical texts. In doing so, he may ask himself who the defining powers are and what interests they have.

As the distinction between health and illness becomes increasingly blurred through the discovery and invention of an infinite number of risk factors,⁴ he may also find that there are other implications of the prevention paradox. Lowering the risk thresholds increases the number of individuals who survive risky behaviours,¹ undermining the reliability of health education messages. Furthermore, if we are faced with a sick population,⁵ it would be fruitful to look for the factors contributing to this. One possible answer is to see the sick population resulting from a "sick society." Whether this society is sick because it promotes lifestyles that result in obesity, hypertension, and hyperlipidaemia or whether it is sick because it is defining half its population as sick remains open to discussion.

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Portable camping stoves continue to cause burns

EDITOR—During four months last summer we treated nine patients who had sustained burns from portable butane camping stoves. The injuries varied from relatively minor burns, usually occurring in the open, to a 60% burn sustained when a canister exploded in the cab of a lorry.

The figure shows a typical injury: 10% mixed depth burns to both legs, which required excision and grafting. This 48 year old man was fitting a butane canister to a portable stove in his kitchen in preparation



10% mixed depth burns to both legs, which required excision and grafting (left); burns were produced by portable camping stove and gas cylinder (right)

for his daughter's camping trip. The canister, which had been bought in a high street camping shop, had no instructions in English on its exterior. He pierced the outer skin of the canister with the sharp point of the burner/valve assembly but was unable to secure it with the metal clips. The butane leaking from the pierced canister was ignited into a fireball by a spark from the electric refrigerator thermostat.

All nine of the patients were injured while changing the canister. There is no fail-safe mechanism to prevent uncontrolled leakage of explosive butane, and if the canister is not secured immediately after it is pierced it acts as a bomb waiting to ignite. Thirteen years ago we drew attention to the danger of these devices¹; since then, the design has not been changed, nor has the frequency of injury.

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1 Saxby PF, Shakespeare PG. Burn injuries from portable butane camping stoves. *Burns* 1985;11:427-8.

White paper on tobacco takes a laudable stance

EDITOR—Whatever the domestic health impact of Britain's new white paper on tobacco,¹ it will resonate loudly and positively around the world. The United Kingdom has done what few countries have done to date—it has formally recognised the global nature of the tobacco problem; accepted the necessity of international efforts to complement concerted domestic action; and acknowledged the responsibility of states to help internationally, both financially and technically.

With tobacco on track to be the world's leading preventable cause of death within a couple of decades, with British health and legislative experience sorely needed around the world, and with a British tobacco company as a chief propagator of this carnage all over the globe, it is right that international tobacco control should move to centre stage at Whitehall.

The white paper's pledge of strong and early support for a Framework Convention

for Tobacco Control is particularly timely. With operations in more than 170 countries, and revenues exceeding the gross domestic product of many countries in which their subsidiaries operate, global tobacco enterprises such as British American Tobacco adroitly sidestep many domestic tobacco control efforts. Spillover advertising, rampant smuggling, and abusive power politics mean that without effective international coordination of control policies, tobacco's present rapid escalation in the developing world will not be halted.

Britain's stance sets the responsible standard other nations must match. Otherwise, these nations will have to account for why they sat silent and let today's one million annual tobacco deaths in the developing world escalate to seven million annually by 2025.

Finally, a single criticism. Though most of the white paper is laudatory, its call for an international code of conduct for transnational tobacco companies, even while awaiting global legal controls on the industry's marketing, is likely to fail, as other voluntary agreements have done. Codes of conduct—voluntary by definition—have long been prominent in the tobacco industry's attempts to forestall effective controls on its activities.

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1 Department of Health. *Smoking kills: a white paper on tobacco*. London: Stationery Office, 1998. (Cm 4177.)

Paying for nicotine replacement therapy is cheaper than smoking ≤ 20 cigarettes a day

EDITOR—Fowler and Smeeth propose making nicotine replacement therapy available on the NHS, believing its high retail price remains prohibitive to many people.¹ A typical eight week course of patches of 21 mg/24 h bought from a pharmacy costs £17 a week, but smokers of 20 cigarettes a day will save roughly £20 a week through not smoking while using the patches.

In the Cochrane systematic review of 47 trials including 23 000 patients, nicotine

replacement therapy doubled smoking cessation rates at 6-12 months compared with placebo.² The authors point out, however, that the absolute probability of abstinence for an individual remains low, and 15 patients would have to use nicotine replacement therapy to produce one extra abstainer. The authors also note that there seems to be evidence of publication bias against negative trials and that compliance with nicotine replacement was lower among smokers treated in primary care.

I am surprised that the editorial overlooks the fact that smokers save money even while paying for their nicotine replacement therapy. This should be borne in mind before yet more pressure is added to the already strained NHS prescribing budget and motivated smokers who currently are using the skills of community pharmacists are encouraged to involve their general practitioner instead.

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Appearance of the hymen in adolescents is not well documented

EDITOR—As forensic paediatricians, we concur with Rogers and Stark's emphasis on the need for education about the nature of the hymen in postpubertal women.¹ Ten of the 20 women described by Logmans et al had been sexually abused.² The appearance of the hymen before puberty and its appearance after sexual abuse has been well described; the appearance of the hymen in adolescents is not well documented. The study by Emans et al³ is an exception.⁴

In 1997 we surveyed 126 consultants at district general hospitals (68 paediatricians, 54 obstetricians and gynaecologists, and four consultants in genitourinary medicine). We wanted to establish the frequency with which they examined the hymen in adolescents and how confident they felt about the clinical findings.

Altogether 91/126 examined the genitalia of adolescents less than five times each year. Only 28/75 routinely assessed the hymen on genital examination. There was uncertainty regarding the significance of findings. A total of 35 out of 75 clinicians did not know if a complete cleft might be an expected finding in adolescent girls who were not sexually active, and 34/75 did not know if it might be expected in sexually active girls. One respondent thought that complete absence of the hymen might be a common finding in girls who were not sexually active; eight respondents thought that it might be a common finding in sexually active adolescent girls. The frequency of congenital absence of

the hymen has been found to be <0.03%.⁵ When asked if they thought that frequent sexual activity resulted in ongoing loss or damage to the hymen, 19 consultants thought that it did, 44 indicated that they did not know, and three said that it did not.

In our experience of examining more than 1000 adolescents who had experienced vaginal penetration the most common appearance of the hymen was of indeterminate disruption to the free edge. Complete clefting or significant gaps in hymenal tissue is unusual.

In the prepubertal girl, because of the relative size of the structures, penetration occurs through the hymenal tissue and causes tearing; in the adolescent girl and adult woman consensual penetration occurs into the orifice which thus stretches and yields, resulting in spreading and indeterminate disruption. We agree with Rogers and Stark that so called rupture and bleeding of the hymen is not to be routinely expected after first sexual intercourse.

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Role of conventional ovarian screening is questioned

EDITOR—It is heartening to read Royle and Waxman's personal view of cancer screening.¹ They say that current screening schedules are predominantly subjective and are heavily based on individuals' interpretation, and proposed that we should pursue the path of molecular screening technologies.

Three postmenopausal women recently presented to our service with advanced ovarian cancer; of note was the fact that they had been evaluated for vaginal bleeding within the past six months. All three had had examination under anaesthesia, hysteroscopy, and curettage of the endometrium, and two had transvaginal ultrasonography. All findings were negative.

This short interval between negative results of clinical evaluation and the appearance of ovarian carcinoma is of concern to us. In Britain the incidence of ovarian cancer is rising; ovarian cancer has become the fourth leading cause of deaths from cancer among women. Over the past 30 years the cost of management per patient has escalated, with no appreciable change in the survival rate.

Current screening modalities to identify early stage, curable disease have been disappointing.² Furthermore, for screening to be worth while in terms of its cost-benefit ratio the minimum interval is normally considered to be one year. The experience with our patients brings into question not only the reliability of pelvic evaluation in identifying ovarian cancer but also the standard time interval of one year.

Conventional screening for ovarian cancer is further complicated by the facts that, unlike cervical and endometrial cancer, there is no well defined preinvasive stage and after five years the postmenopausal ovary shrinks to 0.75 cm³, which is one fifteenth of its premenopausal size. This is important medicolegally and implies that clinically impalpable ovaries cannot exclude an ovarian carcinoma; if they are palpable there is a 10% incidence of malignancy.³

We suggest that women who have been genetically proved to be at high risk of ovarian cancer should be offered prophylactic oophorectomy; those preferring ovarian conservation should be screened with measurement of serum CA 125 antigen concentrations and transvaginal ultrasonography, but at what safe interval? The beneficial effect of prophylactic oophorectomy for women over 40 undergoing pelvic surgery, as well as the positive effect of the combined pill against ovarian cancer, should be emphasised.^{4,5}

If the results of the current large multicentre clinical trials of ovarian screening fail to show benefit then we need to search for better clues via the genetic events that predicate ovarian malignancy.

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Perinatal death associated with planned home birth in Australia

Home births are not justified in Australia

EDITOR—Bastian et al report the risk of perinatal death associated with planned home birth in Australia.¹ I have been criticising the role of home births in Queensland for the past two years, as chairman of the Queensland state committee of the Royal Australian College of Obstetricians and Gynaecologists. In Queensland a registered midwife can (and they do) go into independent mid-

wifery practice after the basic 12 months' training and 20 normal deliveries. Although the College of Midwives has rigid criteria, they are neither enforced nor policed. No one mentions maternal mortality or morbidity.

In two years in Queensland I received reports of one maternal death (a second death was admitted to me by the Queensland state president of the Australian College of Midwives) and one near maternal death requiring hysterectomy and dialysis for three weeks. I was assured that the two maternal deaths were due to amniotic fluid emboli, so would have been unavoidable even in hospital, although I have no records of results of postmortem examinations to prove this. During the same period I documented eight perinatal deaths (to my personal knowledge) out of a total of 400 deliveries by home birth. Queensland also has home birth practitioners who have no insight into their own limitations or what is termed low risk, accepting women pregnant with twins (to deliver in the mountains, and who required helicopter evacuation), with previous caesarean section, and with anti-D antibodies.

I do not believe that home births are justified at present in Queensland, or most parts of Australia, because of inadequate controls, training, supervision, and policing and the immense geographical distances. In a trial of birthing at an Aboriginal homeland (Cherbourg) four perinatal deaths occurred in 80 deliveries,² a figure that I regard as unacceptable. Until the training of domiciliary midwives in Australia reaches the standards of the United Kingdom and the Netherlands, for example, and until these independent midwives are properly policed, and receive adequate back up, home births are not justified.

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1 Bastian H, Keirse MJNC, Lancaster PAL. Perinatal death associated with planned home birth in Australia: population based study. *BMJ* 1998;317:384-8. (8 August.)

2 Queensland Government. *Birthing in homelands for aboriginal and Torres Strait islands*. Brisbane: Queensland Government, 1997.

Study prompts several questions

EDITOR—Retrospective analysis lends itself to two obvious issues of bias—where the author knows what information to look for and therefore unwittingly finds only information that fits the hypothesis; and where the researcher is classifying a cause of death and the underlying pathology may not be documented or searched for, which again allows the author's argument to be strengthened in a certain direction.

The nature and extent of the data—what percentage of births and deaths were reported and to whom—are unstated in Bastian et al's study.¹ Readers are not told which states supplied perinatal data for 1989-90 whether the non-participants in the Homebirth Australia register complied with

these data collections. Eleven deaths were excluded for reasons not stated. Thereafter the authors still refer to 50 deaths but it is not clear whether there were 61 deaths or the minimum data were available on 39.

Birthweight specific data were available for 1985-8 (table 4). Is it possible to calculate a five year mortality without birthweight specific data and without giving the number of known births over five years? The paper does not reference the source of national figures on birthweight specific perinatal mortality or give the years for which the data were available.

Can gestational age and cause of death be ascertained with any certainty through retrospective case analysis without confirmation from a postmortem examination by a perinatal pathologist? What percentage of the intrapartum fetal deaths (table 4) might otherwise have been described as inevitable spontaneous abortions?

Is it justifiable to compare perinatal mortality internationally? The baseline measurement for a fetal death in Australia is 20 weeks, for the United Kingdom 24 weeks, for Norway 16 weeks, and for New Zealand (until recently) 28 weeks. The political, educational, and social determinants for home birth differ widely between Australia and the countries compared, as do the exclusion criteria and the discrepancies in collecting study data.

What is the link between late neonatal deaths and home birth? The five late neonatal deaths (table 3) include death from postviral cardiomyopathy, chromosomal abnormality, and the sudden infant death syndrome. Definitions of late neonatal death and the sudden infant death syndrome are usually mutually exclusive.

Should researchers attempt to draw definitive conclusions with regard to shortcomings in perinatal care, risk assessment, rates and severity of intrapartum asphyxia, cause and time of death, and failure to transfer women safely in a study such as this?

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1 Bastian H, Keirse MJNC, Lancaster PAL. Perinatal death associated with planned home birth in Australia: population based study. *BMJ* 1998;317:384-8. (8 August.)

Authors' reply

EDITOR—Our study shows that low risk home births in Australia have good outcomes but high risk births give rise to a high rate of avoidable death at home. These conclusions may be unpalatable but are supported by an increasing body of evidence.

We agree with Sullivan that home birth practice in Australia needs to be monitored. We also agree that Aboriginal mortality is distressingly high, but this applies throughout Australia, not just to homelands and home births. The conclusion should be to provide birth options and care that are both adequate and culturally appropriate. Our study indicates that most home birth practitioners achieve outcomes that are similar to those internationally.

Sullivan is wrong to suggest that maternal mortality receives no attention in Australia.¹ Tracy is similarly wrong in her understanding of Australian perinatal data. The nature and extent of these data have been fully described^{2,3} (as referenced in our paper). Perinatal data and registration data on births and deaths have been available nationally for many years.

There is no mechanism by which 11 excluded deaths (two excluded because they were unattended and nine because of transfer before labour^{2,3}) can change the 50 included deaths to either 61 or 39. Birthweight specific data were available for over 70% of home births during 1985-90 and close to 80% during 1985-8. "Inevitable spontaneous abortion" is not a term that can be applied to intrapartum fetal deaths (all but two of which occurred at term or after term in this study). Interesting as an international comparison of the lower limits of registration may be, it is not relevant to planned home births or the comparison in our paper. Gestational age is an important predictor of risk in birth, whether at home or in hospital. Postmortem examinations are important in elucidating the cause of death, but contributing clinical factors must also be considered, particularly in establishing whether there is a pattern of avoidable deaths.

Terms such as neonatal death, infant mortality, and the sudden infant death syndrome are not usually mutually exclusive. In Australia any death occurring within 28 days of birth is a neonatal death, regardless of cause. It is disturbing, though, that in Australia the sudden infant death syndrome is seven times more common among births planned at home than among other births (14.6 v 2.1 per 1000; relative risk 6.9 (95% confidence interval 3.1 to 15.3)).⁴ Whether and to what extent this relates to the levels of peripartum oxygen deprivation identified in our study is unknown.⁴

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1 Beischer N (chair). *Report on maternal deaths in Australia 1991-93*. Canberra: National Health and Medical Research Council, Commonwealth of Australia, 1998.

2 Bastian H, Lancaster PAL. *Home births in Australia 1985-1987*. Sydney: AIHW National Perinatal Statistics Unit, 1990.

3 Bastian H, Lancaster PAL. *Home births in Australia 1988-1990*. Sydney: AIHW National Perinatal Statistics Unit, 1992.

4 Lumley J, Sombekke M. Differences in the incidence of sudden infant death syndrome by place of birth: Victoria, Australia, 1985-1987. In: Walker AM, McMillen C, eds. *Second SIDS international conference*. Ithaca, NY: Perinatology Press, 1993:158-60.

Rapid responses



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